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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/321,766	05/28/1999	AWADHESH K. MISHRA	121-176	7018

7590

01/08/2002

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EXAMINER

WEBMAN, EDWARD J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 01/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/321766

Applicant(s)

MISHRA

Examiner

WFBMAN

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 11/8/01
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 23-37 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 23-37 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. in view of Bapatia.

Muller et al teach a Nano particulate drug carrier composition comprising 0.001-30% lecithin (claims 1, 13, 15), the compounds polyvinyl alcohol, poloxamer glucose, mannose trehalose and sorbitol at 0.1-2% (claims 1-22), and 0.1-30% active (claims 1,7). Parenteral, intramuscular, and subcutaneous administration are disclosed (column 6, line 61, column 9 line 33). Antimycotic, corticoid, and immuno therapeutics such as cyclosporin are specified (claims 39, 48).

Bapatia teach heat sterilization of pharmaceuticals under nitrogen to prevent their oxidation (abstract)

It would have been obvious to one of ordinary skill to sterilize the composition of Muller et al under nitrogen to achieve the beneficial effect of preventing oxidation of the active agent therein in view of Bapatia. Applicants point to example 10 with 10% Lipofund in for particle growth. However this composition is a counter example. Column 8 line 21 refers to conditions for lowest particle growth.

Claims 21-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 21-22 line 6 is "modifiers" intended?

In claim 21 line 8 "or a combination" is indefinite in a Markush group with "Selecting from" language. It is suggested that "and mixtures thereof" be made the last member of the group. In claim 21 line 14 line claim 22 "substantially" is vague; what percent?

The disclosure is objected to because of the following informalities: On page 3 second full paragraph line 6 does applicant intend "such A suspension"? In the third full paragraph lines 2-3 is "convert THE lipophilic drug surfaces to hydrophilic drug surfaces" intended? That is, these phrases, as they stand, are grammatically incorrect.

Appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J Webman whose telephone number is 308-0570. The examiner can normally be reached on Monday through Friday from 9 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna F Moezie, can be reached on (703) 308-0570. The fax phone number for the organization where this application or proceeding is assigned is 308-0570.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Webman/LR

January 4, 2002

EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500